AUG 19 2003

Summary of Safety and Effectiveness

Submitter: Address:	BCI, Inc. N7 W22025 Johnson Road Waukesha, WI 53186
Telephone:	(262) 542-3100
Contact:	VP Regulatory Affairs
Prepared:	January 31, 2003
Proprietary Name:	BCI™ Advisor® vital signs monitor (model 9200) with new capnography option.
Common/Classification Name:	Vital signs monitor
Predicate Devices:	BCI™ 9200 vital signs monitor (K982279, K010770, K011177) BCI™ 9004 monitor (K970209) BCI™ 9000 monitor (K873856)

New Device Description:

The BCI 9200 vital signs monitor has been updated to include a new capnography option. This new feature uses the same technology as existing legally marketed devices. This device is designed to provide full featured monitoring capabilities in a table top design. The full system features an ECG cable interface, two invasive pressure interfaces, two YSI 400/700 compatible temperature interfaces, an NIBP cuff hose connection, an SpO_2 sensor interface, a capnography tubing interface and filters, an internal printer, display of patient and waveform data via a color liquid crystal display (LCD), system power status LEDs, a rotary control knob and the function keypad area consisting of five keys (on/off, IP zero, NIBP start/stop, print start/stop and alarm silence). The monitor has analog and serial output ports that are used for data communications to personal computers, printers, chart recorders, or the Life Sensing Instrument Company, Inc. HTS 820 Central Station.

Intended Use:

The 9200 vital signs monitor is intended to be used in the ICU, CCU, OR, ER, RR, Labor and Delivery rooms, special procedure labs and other areas of the hospital or clinic where

low end monitoring systems are needed. The basic monitor package includes ECG (3 lead / 5 lead), impedance respiration (RSP), non-invasive blood pressure (NIBP), pulse oximetry (SpO2), two invasive blood pressures (P1 and P2), and two temperature channels (T1 and T2). Capnography (ETCO2, inCO2, RR), a two-inch internal, graphical/alphanumeric printer and a battery are provided as options. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The device will provide fast, reliable measurements on patients ranging from neonate to adults when using the appropriate BCI accessories. The impedance respiration and capnography parameters are available in adult and pediatric mode only and are not intended for neonatal monitoring. The monitor may be connected to the Life Sensing Instrument Company, Inc. HTS 820 Central Station for remote monitoring of patient status.

The monitor is not intended for home use. The monitor is not intended to be an apnea monitor. It was not designed or validated for use as an apnea monitor.

Performance Data:

The design of this device utilizes currently available technology found in many legally marketed devices. Both hardware and software changes were made to the device. Testing was done to ensure that BCI® 9200 vital signs monitor was safe and would perform within the environments for which it is to be marketed.

Testing was performed in accordance with the guidelines and standards found in the reviewer's guides for respiratory devices. Electromagnetic compatibility (EMC), electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing has been completed. The results demonstrated that the BCI® 9200 vital signs monitor is in compliance with the guidelines and standards referenced in the reviewer's guides and that it performs within its specifications and functional requirements.

Tests were performed to show substantial equivalence of the new device to the predicate devices. Comparison of the new capnography feature was made to BCI® 9000 monitor's capnography function using both bench and clinical tests. Comparisons of all other parameters were made with the previous BCI® 9200 vital signs monitor using bench tests.

Testing of device performance included clinical testing of the $ETCO_2$ and respiration rate measurements made by the BCI® 9200 vital signs monitor. Further performance testing of the capnography parameter was also conducted in accordance with EN 864 (international standard for capnography). In addition, a human factors review and long term alarm test were performed to demonstrate overall device performance. The results demonstrated that the BCI® 9200 vital signs monitor performed within its specifications.

A full software validation test of the BCI® 9200 vital signs monitor with new capnography option was completed. These tests showed that the device modifications operate as intended and that the changes made do not compromise the overall performance of the monitor.

On the basis of these results, it is our determination that the device is safe, effective, and performs as well as the legally marketed predicate device(s).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully,

Donald Alexander
VP Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2003

BCI, Inc.
c/o Mr. Donald J. Alexander
VP Regulatory Affairs
N7 W22025 Johnson Road
Waukesha, WI 53186

Re: K030407
Trade Name: BCI™ Advisor® Vital Signs monitor (model 9200) with new capnography option
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon-Dioxide Gas Analyzer, Gaseous-Phase
Regulatory Class: Class II (two)
Product Code: CCK
Dated: June 6, 2003
Received: June 9, 2003

Dear Mr. Alexander:

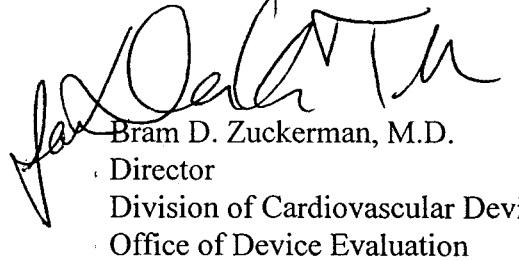
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030407

Indications For Use

510(k) Number (if known): K030407

Device Name: BCI 9200 Vital Signs Monitor with Capnography.

Indications For Use:

Intended Use

The 9200 vital signs monitor is intended to be used in the ICU, CCU, OR, ER, RR, Labor and Delivery rooms, special procedure labs and other areas of the hospital or clinic where low end monitoring systems are needed. The basic monitor package includes ECG (3 lead / 5 lead), impedance respiration (RSP), non-invasive blood pressure (NIBP), pulse oximetry (SpO_2), two invasive blood pressures (P1 and P2), and two temperature channels (T1 and T2). Capnography ($ETCO_2$, $inCO_2$, RR), a two-inch internal, graphical/alphanumeric printer and a battery are provided as options. The device permits patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. The device will provide fast, reliable measurements on patients ranging from neonate to adults when using the appropriate BCI accessories. The impedance respiration and capnography parameters are available in adult and pediatric mode only and are not intended for neonatal monitoring. The monitor may be connected to the Life Sensing Instrument Company, Inc. HTS 820 Central Station for remote monitoring of patient status.

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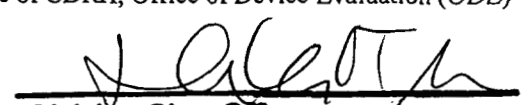
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030407

Prescription Use X OR Over-The_Counter Use _____
(Per 21 CFR 801.109)